

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

CONSUMER HEALTH INFORMATION CORPORATION,)	CASE NO. 1:13-CV-01061
)	
)	
Plaintiff,)	
)	
v.)	
)	
AMYLIN PHARMACEUTICALS, INC.,)	
AMYLIN PHARMACEUTICALS, L.L.C.)	
and ELI LILLY & CO.)	
)	
Defendants.)	

**COMPLAINT
(DEMAND FOR JURY TRIAL)**

Plaintiff Consumer Health Information Corporation files this Complaint and asserts the following allegations and claim against Defendants Amylin Pharmaceuticals, Inc., Amylin Pharmaceuticals, L.L.C., and Eli Lilly & Co. and would respectfully show the Court the following:

I. PARTIES

1. Plaintiff Consumer Health Information Corporation is a corporation incorporated under the laws of the District of Columbia with its principal place of business in the State of Virginia.

2. Defendant Amylin Pharmaceuticals, Inc. ("Amylin") is a corporation incorporated under the laws of the State of Delaware with its principal place of business in the State of California, and may be served with process by serving its registered agent, CT Corporation System, 818 W. Seventh Street, Los Angeles, California 90017. Amylin Pharmaceuticals, Inc. is believed to now be a wholly-owned subsidiary of Bristol-Myers Squibb.

3. Defendant Amylin Pharmaceuticals, L.L.C. ("Amylin") is a limited liability company formed under the laws of the State of California with its principal place of business in the State of California, and may be served with process by serving its registered agent, CT Corporation System, 818 W. Seventh Street, Los Angeles, California 90017. Amylin Pharmaceuticals, L.L.C. is believed to now be a wholly-owned subsidiary of Bristol-Myers Squibb.

4. Defendant Eli Lilly & Co. ("Lilly") is a corporation incorporated under the laws of the State of Indiana with its principal place of business in the State of Indiana, and may be served with process by serving its registered agent, Michael J. Harrington, Eli Lilly & Co., Lilly Corporate Center, 893 S. Delaware St, Indianapolis, Indiana 46225.

II. VENUE AND JURISDICTION

5. Venue is proper in this judicial district because one or more Defendants and/or their agents reside or may be found in this judicial district. 28 U.S.C. § 1400.

6. This Court has subject matter jurisdiction over this civil action pursuant to 28 U.S.C. § 1338.

III. FACTS

7. In 2005, Defendants introduced the pharmaceutical drug BYETTA to the marketplace. Defendants are companies primarily engaged in the research, development, manufacture, marketing, and sale of pharmaceutical medicines and devices.

8. BYETTA is an injectable prescription medicine that may improve blood sugar (glucose) control in adults with type 2 diabetes mellitus. Defendants worked together to

research, develop, manufacture, market, and sell BYETTA as part of a mutual alliance between the entities. Defendants' alliance was named and referred to as the Amylin-and-Lilly Alliance. As part of their alliance, Defendants agreed to share in the costs incurred and profits derived from BYETTA.

9. After the launch of BYETTA, Defendants experienced poor sales and extremely high call center costs. The poor sales were the result of poor patient adherence and patient compliance. Patients had a difficult time understanding the materials that came with their medication and, thus, had a difficult time administering the drug properly. Many patients stopped taking BYETTA because of these difficulties. As a result, patients stopped re-filling their BYETTA prescriptions. These factors led to poor sales.

10. In addition, the materials provided to physicians and other healthcare professionals did not adequately train these persons how to demonstrate the proper use of BYETTA to their patients. As a result, physicians did not prescribe BYETTA as frequently as expected. This factor also led to poor sales.

11. In November 2005, Defendants contacted Consumer Health Information Corporation ("CHIC") to develop a strategy to improve the sales of BYETTA by improving patient understanding of how to use the medication and by motivating patients to stay in treatment. CHIC is an entity with expertise in patient engagement and patient adherence strategies, health literacy, and patient education program development for prescription drugs, over-the-counter products, and medical devices. CHIC originally provided ten hours of consulting services to Defendants. Defendants did not pay CHIC for the original consulting services until months later after the parties entered into a Master Service Agreement.

12. In December 2005, Defendants requested CHIC to develop a patient-compliance strategy that would increase patient adherence and, in turn, increase the sales of BYETTA. CHIC provided these services to Defendants. During the course of work, Defendants requested an unusually high number of revisions to CHIC's proposals, and CHIC was never paid for this work.

13. In January 2006, Defendants continued to assign CHIC work with the assurance that the proposal was in the approval process. Likewise, Defendants continually reassured CHIC that the payment for CHIC's prior work would be forthcoming as soon as the proposal was approved.

14. In February 2006, Defendants advised CHIC that Defendants had decided to change the scope of work and that they would no longer be doing a patient-compliance strategy. Defendants, therefore, requested CHIC to develop a different proposal to create and to develop new patient education materials for BYETTA.

15. CHIC later realized that Defendants' goal for the first quarter of 2006 was to develop a patient-compliance strategy. CHIC provided this strategy to Defendants prior to February 2006. Instead, Defendants obtained their first quarter goal through CHIC for free and, having already met their goal, Defendants switched CHIC's scope of work from a patient-compliance strategy to a patient-education project.

16. From February 2006 through March 2006, Defendants continued to request CHIC to make revisions to CHIC's patient-education proposal. During this same period of time, Defendants continued to assign work to CHIC with the promise that the proposal was being approved. Defendants requested CHIC to develop a multicomponent schedule and many rush

revisions that would ensure that the projects covered under the patient-education proposal would be completed by Summer 2006. CHIC continued to do significant work on the patient-education project for Defendants. As a result, CHIC became significantly involved in the project and incurred more than a hundred thousand dollars in time and expenses.

17. During this same time period, Defendants requested invoices from CHIC on CHIC letterhead for the first two quarters of 2006. Defendants told CHIC the amount to be billed on each invoice. CHIC believed that its proposal was almost approved and that Defendants would pay CHIC for these two invoices.

18. By mid-March 2006, CHIC threatened to stop work on the project until CHIC's proposal was approved and payment for all past work on the patient-education project was received. In response, Defendants approved CHIC's proposal. Defendants, however, did not execute or return CHIC's proposed Master Service Agreement. Instead, Defendants offered a consultancy agreement to Dorothy L. Smith, Pharm.D., who serves as CHIC's Chief Executive Officer.

19. CHIC required that the Master Service Agreement be under CHIC's name, not Dr. Smith's name. Defendants agreed to a Master Service Agreement with CHIC, but changed the language governing the assignment of copyrights. Defendants insisted that CHIC agree to Defendants' copyright language.

20. By this time, CHIC had expended significant time and expenses in furtherance of the project. Based on CHIC's financial condition at the time, CHIC was in severe jeopardy of imminent financial ruin in the event that Defendants did not tender payment for the services already rendered. For example, CHIC had negative equity, owed hundreds of thousands of

dollars in outstanding debt, and had devoted the entirety of its manpower and focus for multiple months on the project. Likewise, CHIC's stock in trade was as much dependent on its reputation in the pharmaceutical industry as its actual work product. Defendants refused payment unless and until CHIC signed Defendants' Master Service Agreement. Based on its financial condition, its interest in preserving its reputation in the marketplace, and Defendants' refusal to tender the significant past-due payments until Defendants' Master Service Agreement was executed, CHIC had no reasonable alternative but to execute Defendants' Master Service Agreement. CHIC, therefore, executed the Master Service Agreement ("MSA") under economic duress in late March 2006.

21. Under the MSA, CHIC was retained to provide patient education services to Defendants, including the development and revision of BYETTA patient education materials. Specifically, Defendants retained CHIC to develop the following patient education materials: the BYETTA Patient Starter Kit (including the Patient Starter Kit Letter, Patient Information Guide and Top 10 FAQ's, a DVD script, Quick Reference Guide, Business Reply Card, Packaging Consultation); the BYETTA User Friendly Manual; the BYETTA Travel Pack and Instructions; and the BYETTA Teaching Tools. In addition to developing these materials, CHIC was contracted to create up to two revisions to the content and layout of each patient education material.

22. In Section 4(a) of the MSA, the parties purported to designate CHIC's creation of the patient education materials as works made for hire under 17 U.S.C. § 101 and, in turn, CHIC purported to assign its interest in the work-for-hire copyrights to Defendants.

23. The patient education materials created by CHIC, however, are not works for hire. The patient education materials are not “instructional texts.” The materials are not “textbook materials.” The materials are not used and were not designed to be used in “systematic instructional activity.” The materials are not the general equivalent of a “curriculum.” The materials are not part of a teaching method established by an educational institution or the government. Rather, the materials were prepared for general readership for use in marketing a pharmaceutical product commercially, both nationally and internationally. Because the patient education materials are not works for hire under 17 U.S.C. § 1, CHIC did not transfer any interest in copyright to Defendants through section 4 of the MSA.

24. Throughout the year, CHIC created the following works: 3 versions of the BYETTA Airline Travel Letter; 3 versions of the BYETTA DVD Label; 9 versions of the BYETTA Patient Information Guide; a large volume of photographs for several projects; 3 versions of the BYETTA Prescription Sticker; 9 versions of the BYETTA Quick Reference Guide; 10 versions of the BYETTA Patient Starter Kit Business Reply Card; 10 versions of the BYETTA Patient Starter Kit Letter; 9 versions of the BYETTA Patient Starter Kit Box; 5 versions of the BYETTA Teaching Tools; 8 versions of the BYETTA Thank You Letter; 10 versions of the BYETTA Travel Pack Business Reply Card; 6 versions of the BYETTA Travel Pack Welcome Letter; 8 versions of the BYETTA Travel Pack Instructions; 6 versions of the BYETTA User Manual; 6 versions of the BYETTA User Manual New; 4 versions of the BYETTA Video Label; and 2 versions of the BYETTA Video Script. Several of these works were not covered by the MSA, and most of the versions of these works were not covered by the MSA. As the creator/author of these works, CHIC owns the copyright in each of the works.

25. Defendants paid for some of CHIC's services through September 30, 2006. After the end of September, Defendants continued to demand work product from CHIC. Defendants, however, failed and/or refused to pay for any work product performed after September 30, 2006.

26. CHIC later learned that Defendants did not pay CHIC for any post-September work product because Defendants had already exhausted their budget. Based on Defendants' initial, prolonged refusal to pay for work prepared before execution of the MSA, Defendants' refusal to pay for all the work prepared before September 30, 2006, and Defendants' refusal to pay for work prepared after September 30, 2006, Defendants entered into the MSA without any intention of fulfilling the terms of the MSA yet represented to CHIC that it would pay for all services rendered. Defendants' representations were material to CHIC's decision to enter the MSA. CHIC reasonably relied on Defendants' misrepresentations to enter into the MSA and suffered harm as a result of entering into the MSA.

27. Throughout the last seven years, including continuing acts of copyright infringement in the last three years, Defendants have copied and used CHIC's works in an effort to derive profits from the marketing and sale of BYETTA. Defendants have earned gross profits in excess of several billions of dollars from the use, copying, and publication of CHIC's works. Defendants were not authorized to use, copy, or publish CHIC's works. Defendants' profits rightfully belong to CHIC.

IV. CAUSES OF ACTION
Copyright Infringement

28. CHIC adopts and incorporates by reference each and every allegation set forth above.

29. CHIC owns a valid copyright over the works it created as referenced above. CHIC did not transfer its copyright interest to Defendants. CHIC's works are not works for hire under 17 U.S.C. § 101. The MSA was procured through economic duress. The MSA was procured through fraud and deceit.

30. Defendants copied constituent elements of CHIC's works that were original to CHIC.

31. CHIC has satisfied all prerequisites to filing this civil action as it has applied for copyrights in the above-referenced works.

32. CHIC has suffered damages as a result of Defendants' copyright infringement.

V. DAMAGES

33. CHIC adopts and incorporates by reference each and every allegation set forth above.

34. As a direct and proximate result of Defendants' copyright infringement, CHIC has incurred actual damages. In addition, CHIC is entitled to all profits received by Defendants that are attributable to the infringement.

VI. JURY DEMAND

35. CHIC demands a trial by jury.

VII. INTEREST

36. CHIC seeks to recover pre-judgment and post-judgment interest as allowed by law.

VIII. **PRAYER**

37. CHIC prays that Defendants be cited to appear and answer herein; that upon final trial hereof, CHIC recovers damages as specified above from the Defendants, attorneys' fees, costs of court, and pre-judgment and post-judgment interest at the legal rate and in an amount to be determined by a jury within the jurisdictional limits of the Court; and that CHIC have such other and further relief, general and special, at law and in equity, to which it may be justly entitled under the facts and circumstances.

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